INTERNATIONAL STANDARD

ISO 11608-2

Second edition
2012-04-01

Needle-based injection systems for medical use — Requirements and test methods —

Part 2: Needles

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —

Partie 2: Aiguilles

Reference number
ISO 11608-2:2012(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11608-2 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 11608-2:2000), which has been technically revised.

ISO 11608 consists of the following parts, under the general title *Needle-based injection systems for medical use — Requirements and test methods*:

— *Part 1: Needle-based injection systems*

— *Part 2: Needles*

— *Part 3: Finished containers*

— *Part 4: Requirements and test methods for electronic and electromechanical pen-injectors*

— *Part 5: Automated functions*

Introduction

This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with needle-based injection systems (e.g. pen injectors). These needles are often referred to as pen needles.

The devices described in this part of ISO 11608 are designed to be used with the devices described in ISO 11608-1 and ISO 11608-3.

The first edition of this part of ISO 11608 introduced the concept of interchangeability and the labelling designations “Type A” (i.e.interchangeable) and “non-Type A” for needles and container closure systems. Since its promulgation, experience has shown that the complexity of these systems makes it very difficult to ensure functional compatibility as defined in the different parts of this International Standard, particularly when products are made by different manufacturers and the design is not verified as a system. Based on this experience, it is believed that the Type A designation does not represent adequate guidance to the user in making decisions on the compatibility of needles and container closures with specific needle-based injection systems (NIS). As such, the labelling designation “Type A” has been removed.

This second edition of ISO 11608-2 addresses functional compatibility of the system through testing in accordance with Clause 11. Flow rate is introduced as a new parameter. The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer’s ability to manufacture one “lot” of needles that conforms to the critical product attributes. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, for example ISO 9000.

This part of ISO 11608 does not specify requirements or test methods for freedom from biological hazards because no international agreement on the methodology and the pass/fail criteria has been reached. Guidance on biological tests relevant to double-ended needles is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such evaluation should include the effects of the sterilization process. However, national regulations might exist in some countries, which might take precedence over the guidance in ISO 10993-1.

In some countries, national regulations exist and their requirements might supersede or complement this part of ISO 11608.

Needle-based injection systems for medical use — Requirements and test methods —

Part 2: Needles

1 Scope

This part of ISO 11608 specifies requirements and test methods for single-use, double-ended, sterile needles for needle-based injection systems (NISs) that fulfil the specifications of ISO 11608-1.

It is not applicable to:

— needles for dental use;

— pre-filled syringe needles;

— needles pre-assembled by the manufacturer;

— needles not requiring assembly or attachment to the NIS.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ISO 11608-1, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

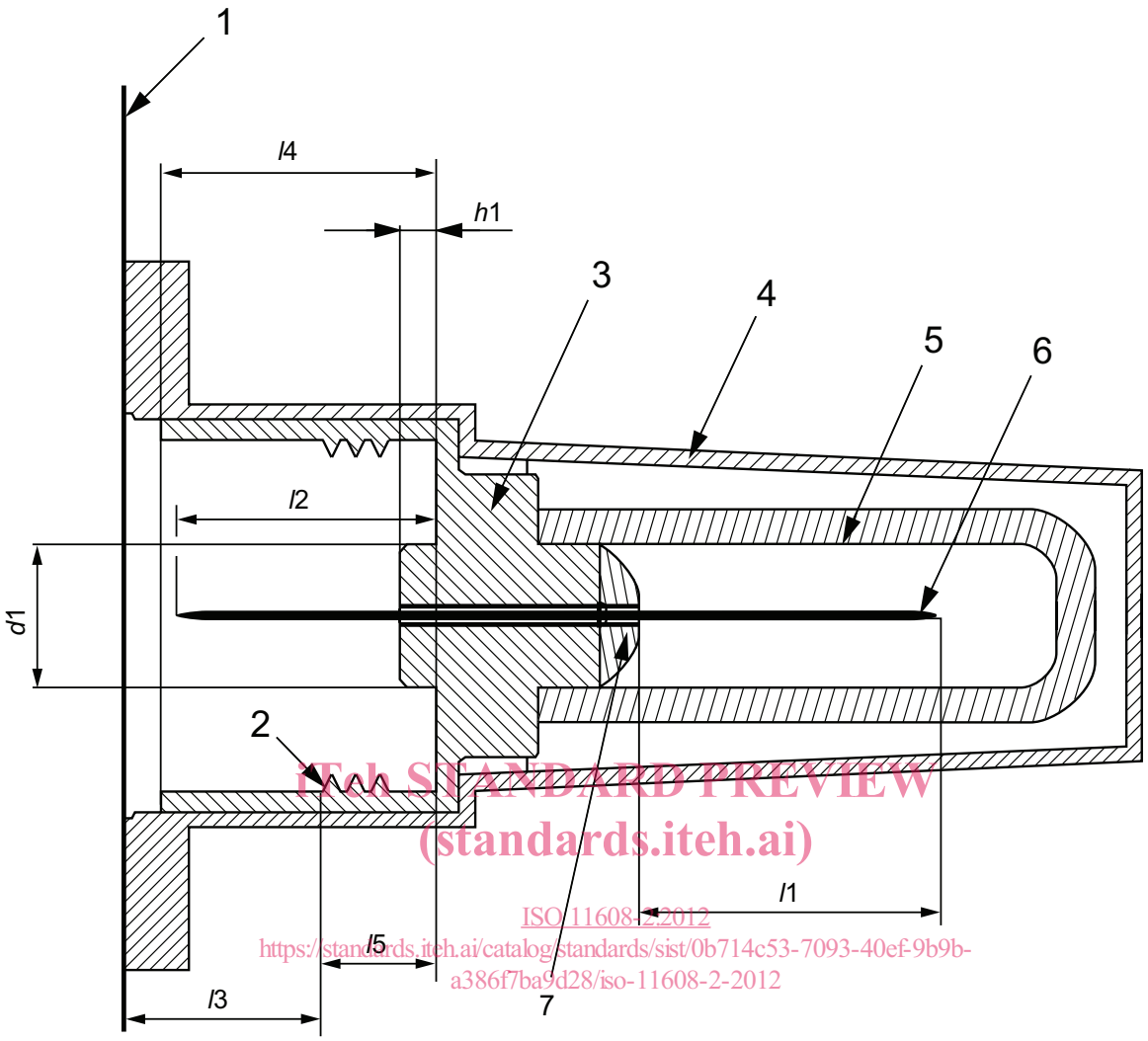
IEC 60068-2-30:2005, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
NIS
needle-based injection system
system intended for parenteral administration by injection of medicinal products using a multi-dose or single-dose container

See Figure 1.



Key

1 seal
2 means of needle assembly attachment
3 needle hub
4 needle container
5 needle shield (not required)
6 needle tube
7 jointing medium (if used)

NOTE The needle container may serve as a needle shield.

Figure 1 — Example presentation of needle assembly for a NIS

3.2
seal
removable barrier which is intended to maintain the sterility of the needle inside the needle container

3.3
unit packaging
needle container, together with the seal forming the packaging of the device, that maintains the sterility of the needle

3.4
user packaging
what is provided to the user with one or a collection of devices, in their unit packaging, of the same item and from the same manufacturing batch

4 Requirements

4.1 Materials

The needle shall be made of tubing materials specified in ISO 9626 or ISO 15510. The requirements in ISO 9626 apply.

4.2 Dimensions

4.2.1 General

The dimensions of the needle assembly attachment part shall be such that the needle fits and functions with NISs that meet the requirements specified in 11608-1.

The tubing characteristics used in needles shall meet the requirements of ISO 9626. If the tubing is not covered in that International Standard, the requirements for stiffness and breakage shall be adapted to corresponding requirements for the defined sizes.

4.2.2 Dimensions for needles

Needles shall fit the test apparatus specified in 7.3. Dimensions shall be in accordance with Table 1.

Table 1 — Dimensional requirements of needle assembly

Measurements	Dimensions mm
l_1	specified length ±1,25
l_2	5,7 to 7,0
l_3	<6,0
l_4	<7,5
l_5	<3,7
h_1	0 to 1,0
d_1	0 to 3,0

Needles may be deliberately designed not to fit the test gauge described in 7.3 and not to meet the dimensional requirements given in Table 1. In such cases, a dedicated test gauge for the specific design shall be created in order to perform the test in 4.8. In addition, the remaining requirements, other than those in 4.2.2, shall apply. In cases where the dimensional requirements of 4.2.2 are not met, the labelling shall state that the needle be used exclusively with the NIS designed for, and tested with, this needle.

4.3 Determination of flow rate through the needle

The needle shall be tested in accordance with Annex A to determine the flow rate through the needle, in millilitres per minute. In addition to complying with the labelling requirements of Clause 12, the flow rate shall be made available on request.

NOTE The flow rate parameter is not a strict requirement of Clause 12, but may be of interest for a NIS manufacturer or other party. Flow rate is an important factor in the overall NIS system performance, as is the injection force and injection time.

4.4 Bond between hub and needle tube

The union of the hub and needle tube shall not break when tested in accordance with Clause 9.

4.5 Needle points

When examined under a magnification of ×2,5, needle points shall appear sharp and free from feather edges, burrs and hooks.

The needle point at the cartridge end shall be designed so as to minimize coring and fragmentation when penetrating the cartridge septum.

4.6 Freedom from defects

The needle tube shall fulfil the requirements of ISO 7864:1993, 11.3.

4.7 Lubrication

The needle tube shall be lubricated at both the patient end and the cartridge end. The lubricant shall not, under normal or corrected-to-normal vision, be visible as droplets of fluid on the outside surface of the needle tube.

4.8 Dislocation of measuring point at patient end

Dislocation of the cannula point at the patient end shall be in accordance with Table 2 when tested in accordance with Clause 8.

Table 2 — Maximum allowable dislocation at patient end

Patient-end needle length l_1 mm	Maximum allowable dislocation d_{max} mm
8	0,9
12	1,1
16	1,4
Others	$0,07 \times l_1 + 0,3$

4.9 Determination of functional compatibility with needle-based injection systems

Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11. Functional requirements are also defined in other parts of ISO 11608 and in the instructions for use of the NIS.

4.10 Ease of assembly and disassembly

Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11.

4.11 Sterility

The needle in its unit packaging shall have been subjected to a validated sterilization process.

5 Sampling

Select 350 needles.

Use 50 needles for the first sample test cycle (sample 1). If two or more needles do not meet the test criteria, the needle type in question is rejected. However, the needle type cannot be accepted based on this first sample alone.

If the needle type is not rejected on the first sample test cycle, perform a test cycle incorporating a second sample of 50 needles (sample 2). If three or more needles fail the test, the batch shall be rejected. If no needles fail the test, the needle type is accepted.

If two needles for sample 1 or three needles for sample 2 fail the test, select a third sample of 50 needles and continue down the table, using the acceptance and rejection test criteria shown in Table 3.

Table 3 — Sampling plan and acceptance/rejection criteria

Sample number	Sample size	Cumulative sample size	Acceptance criteria[a]	Rejection criteria[a]
1	50	50	N/A[b]	2
2	50	100	0	3
3	50	150	0	3
4	50	200	1	4
5	50	250	2	4
6	50	300	3	5
7	50	350	4	5

NOTE The numbers in the table are derived from the original version in ISO 2859-1.

[a] Number of needles.

[b] Acceptance not permitted at this stage.

6 Pre-conditioning of needles

6.1 Pre-conditioning in a dry-heat atmosphere

Place the needle within its unit packaging in a test chamber for at least 96 h in the following atmosphere:

— temperature: (70 ± 2) °C;

— relative humidity: (50 ± 10) %RH.

6.2 Pre-conditioning in a cold-storage atmosphere

Place the needle within its unit packaging in a test chamber for at least 96 h in the following atmosphere:

— temperature: (−40 ± 3) °C.

6.3 Pre-conditioning in a cyclical atmosphere

Place the needle within its unit packaging in a test chamber. Carry out conditioning in accordance with IEC 60068-2-30 as follows:

— variant 1 [see IEC 60068-2-30:2005, Figure 2 a)];

— lower temperature: (25 ± 3) °C (no humidity requirement);

— upper temperature: (55 ± 2) °C;

— six cycles.

NOTE The relevant clauses of IEC 60068-2-30:2005 are Clause 4 (testing chamber), Clause 7 (conditioning) and Clause 9 (recovery).